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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,403	07/02/2001	Kenneth William Hunt	VAC.705.US	9206
60402	7590	11/14/2007		
KINETIC CONCEPTS, INC. ATTN: LEGAL DEPARTMENT INTELLECTUAL PROPERTY P.O. BOX 659508 SAN ANTONIO, TX 78265			EXAMINER HAND, MELANIE JO	
			ART UNIT	PAPER NUMBER
			3761	
			MAIL DATE	DELIVERY MODE
			11/14/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/807,403

Applicant(s)

HUNT ET AL.

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/10/07</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 10, 2007 has been entered.

### ***Response to Amendment***

The affidavit under 37 CFR 1.132 filed August 10, 2007 is sufficient to overcome the rejections of claims 1-15 based upon the Hunt reference.

### ***Response to Arguments***

Applicant's arguments, see Remarks, filed August 10, 2007, with respect to the rejection(s) of claim(s) 1-15 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a newly found prior art reference.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lina et al (WO 96/05873 A1).

With respect to **claim 1**: Lina teaches an apparatus for applying negative pressure therapy to a wound site, which comprises an open celled foam pad 36 for application to the wound, a suction tube in the collective form of hoses 37 and 38 connecting the foam pad 36 to a collection canister 19, a tube 62 connecting the canister 19 to a vacuum pump 84, and a pressure detector in the form of transducer 75 connected to tube 62 via branch tube 93 for indicating when the pressure in the suction tube 37,38 (which is equal to the pressure in tube 62 due to the dampening effect contributed by restrictor 89) crosses a predetermined level.

Lina does not explicitly teach a wall suction source, however a wall suction source is an example of a vacuum pump and performs a substantially identical function to the vacuum pump taught by Lina. Thus, it would be obvious to one of ordinary skill in the art to substitute a wall suction source for the suction pump taught by Lina with a reasonable expectation of success to ensure that the suction function of the instant apparatus is preserved while the device is stationary or when the device is used portably with the instant vacuum pump.

Lina does not teach that the pressure detector 75 is connected by a branch tube to suction tube 37,38 leading from the foam pad 36 to the canister 19. However, Lina does teach that restrictor 89 acts as a damper to pressure changes in tube 62 (i.e. effectively zeroing the pressure changes in tube 62) whose dampening effects cause the pressure measured by transducer 75 to be an accurate indication of actual wound site pressure. Since the pressure detector 75 is effectively measuring only wound site pressure, it would be obvious to one of ordinary skill in the art to modify the apparatus of Lina such that transducer 75 is connected by a branch tube to suction tube 37,38 leading from the foam pad 36 to the canister 19 with a reasonable expectation of success to preserve the transducer's function of measuring pressure at the wound site. (Page 17, ¶ 2)

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Lina teaches that said canister 19 has filter cap 49 that closes an outlet 44 from the canister 19 that is manually operable at any time, including when the canister 19 is full. Filter cap 49 is not explicitly a valve. However since the cap 49 functions as a valve in that it prevents exudate from flowing out of outlet 44 and ultimately contaminating the pump 84, or can allow suction flow to resume when a new empty canister 19 is positioned within the apparatus, it would be obvious to one of ordinary skill in the art to modify the apparatus of Lina so as to include a shut off valve in addition to the filter cap 49 with a reasonable expectation of success, as the primary purpose of the filter cap 49 as taught by Lina is not to regulate flow (though it can) but to prevent contamination of filter body 48. (Page 7, ¶3, Page 10, ¶3, Page 17, ¶¶ 1-3)

With respect to **claim 2**: The apparatus taught by Lina further comprises a flow limiting valve in the form of restrictor 89 between the canister 19 and the suggested wall suction-point 84, the flow limiting valve 89 allowing adjustment of the flow to a selected rate such that flow in the tube 62 does not exceed the selected rate. (Page 17, ¶ 2)

With respect to **claim 3**: The apparatus taught by Lina includes a pressure relief valve in the form of bleed valve 86 which is connected to the suction tube 62 between the foam pad 36 and the canister 19. (Page 16, ¶3)

With respect to **claim 4**: Lina fairly suggests a pressure detector connected to the suction tube 37,38 between the foam pad 36 and the canister 19 comprising a second transducer 75 for reasons stated *supra* with respect to claim 1.

Lina does not explicitly teach a first transducer for measuring pressure in the tube 62 linking the canister 19 to a wall suction point. However, since Lina does teach the presence of

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bleed valve 86, which is a pressure regulator as the regulator is disclosed by applicant. Valve 86 prevents over pressurization and enables intermittent application of negative pressure, allowing gradual release of the negative pressure when the pump motor 83 is deactuated. Since the valve 86 acts as a pressure regulator whose function is indirectly controlled by microprocessor 72 via pump motor 83, it would be obvious to one of ordinary skill in the art to modify the apparatus of valve 86 so as to convert it to a transducer by supplying a means for outputting a signal indicating pressure in line 62 adjacent the valve that is received by controller 72 to provide a feedback loop that enables improved sensing regulation and operation of the vacuum pump 84 by converting valve 86 into a functioning transducer. (Page 17, ¶¶ 1-3)

With respect to **claims 5,6**: The flow rate meter in the form of fill sensor 64 measures the rate at which the canister is filled. Since such fluid is drawn directly to the canister 19, the rate at which fluid is drawn from the wound site is also the rate at which the canister 19 is filled. Thus the flow rate meter 64 necessarily also measures the rate at which fluid is drawn from the wound site.

(Page 11, ¶3)

With respect to **claim 7**: The flow rate meter 64 is a capacitive sensor and thus is an electrical capacitance measuring device. (Page 11, ¶3)

With respect to **claim 8**: Lina teaches an apparatus 10 for applying negative pressure therapy to a wound site, which comprises an open-celled foam pad 36 for application to the wound, a suction tube in the collective form of hoses 37,38 connecting the foam pad 36 to a collection canister 19, a tube 62 connecting an outlet 44 of the canister to a wall suction point 84, a sensor in the form of fill sensor 64 operable to detect when the canister 19 is full.

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Lina teaches that said canister 19 has filter cap 49 that closes an outlet 44 from the canister 19 that is manually operable at any time, including when the canister 19 is full. Filter cap 49 is not explicitly a valve. However since the cap 49 functions as a valve in that it prevents exudate from flowing out of outlet 44 and ultimately contaminating the pump 84, or can allow suction flow to resume when a new empty canister 19 is positioned within the apparatus, it would be obvious to one of ordinary skill in the art to modify the apparatus of Lina so as to include a shut off valve in addition to the filter cap 49 with a reasonable expectation of success, as the primary purpose of the filter cap 49 as taught by Lina is not to regulate flow (though it can) but to prevent contamination of filter body 48. (Page 7, ¶3, Page 10, ¶3, Page 17, ¶¶ 2,3)

With respect to **claim 9**: The apparatus taught by Lina includes means for giving a warning that the canister is full in the form of alarm 95 and for shutting off the connection between the canister 19 and the wall suction point suggested by Lina in the form of microcontroller 72 that outputs a signal that deactivates pump motor 83 and fan 74. The means for giving a warning taught by Lina anticipates the claimed means as it is disclosed, i.e. a visual indication on a display or an audible alarm. As to the means for shutting off the connection, such means is not sufficiently defined in the disclosure and thus the claim is interpreted as being unpatentable over the means for shutting off the connection taught by Lina as an "equivalent thereof" of the claimed means in accordance with 35 U.S.C. 112, sixth paragraph. (Page 18, ¶ 3)

With respect to **claim 10**: The apparatus taught by Lina includes means for monitoring pressure at the wound site, as the means is disclosed by applicant, in the form of transducer 75, which effectively monitors pressure at the wound site because, while transducer 75 is connected to tube 62 via branch tube 93 and not either of tubes 37 or 38, due to the dampening effect of

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restrictor 89 on pressure changes within tube 62, the transducer 75 gives an accurate measurement of pressure at the wound site. (Page 17, ¶ 2)

With respect to **claim 11**: The apparatus taught by Lina further includes means for regulating pressure between the canister 19 and the wall suction point 84 in the form of a relief valve, i.e. bleed valve 86. (Page 16, ¶3 - Page 17, ¶ 1)

103 With respect to **claim 12**: The pressure detector comprises a transducer 75 connected by a branch tube 93 to tube 62 connecting canister 19 to wall suction 84. Lina does not teach that the pressure detector 75 is connected by a branch tube to suction tube 37,38 leading from the foam pad 36 to the canister 19. However, Lina does teach that restrictor 89 acts as a damper to pressure changes in tube 62 (i.e. effectively zeroing the pressure changes in tube 62) whose dampening effects cause the pressure measured by transducer 75 to be an accurate indication of actual wound site pressure. Since the pressure detector 75 is effectively measuring only wound site pressure, it would be obvious to one of ordinary skill in the art to modify the apparatus of Lina such that transducer 75 is connected by a branch tube to suction tube 37,38 leading from the foam pad 36 to the canister 19 with a reasonable expectation of success to preserve the transducer's function of measuring pressure at the wound site. (Page 17, ¶ 2)

With respect to **claim 13**: The apparatus taught by Lina further comprises a processor in the form of microcontroller 72 operationally coupled to the relief valve 86 and programmed to provide intermittent negative pressure therapy to the wound site. (Page 17, ¶¶ 1,3, Page 18, ¶1)



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With respect to **claim 14**: Lina teaches an apparatus for applying negative pressure therapy to a wound site, the apparatus comprising: an open-celled foam pad 36 for application to the wound; a suction tube in the collective form of hoses 37,38 connecting the foam pad 36 to a collection canister 19; a pressure regulator in the form of restrictor 89 fluidly connected between the canister 19 and vacuum pump 84; and a processor in the form of microcontroller 72 in electronic communication with the pressure regulator 89 to regulate the pressure from said vacuum pump 84 to the collection canister 19.

Lina does not explicitly teach a wall suction source, however a wall suction source is an example of a vacuum pump and performs a substantially identical function to the vacuum pump taught by Lina. Thus, it would be obvious to one of ordinary skill in the art to substitute a wall suction source for the vacuum pump taught by Lina with a reasonable expectation of success to ensure that the suction function of the instant apparatus is preserved while the device is stationary or when the device is used portably with the instant vacuum pump. (Page 7, ¶3, Page 17, ¶¶ 2,3)

With respect to **claim 15**: The pressure regulator includes a relief valve in the form of bleed valve 86 along tube 62, and wherein the processor 72 is configured to actuate the relief valve 86 to relieve pressure in tube 62, which, due to the action of restrictor 89 as described with respect to claim 12 *supra* is equal to pressure at the wound site, when pressure at the wound site reaches a set maximum pressure. (Page 16, ¶3, Page 17, ¶3)

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on M-Th 8-5, alt Fri. 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand  
Examiner  
Art Unit 3761

November 1, 2007

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

